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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Examiner: Duffy, P. TECH CENTER 1600/2900

Heath et al.

Group Art Unit: 1645

Serial No.: 08/699,716

Atty Docket: 003/029/SAP

Filed: August 27, 1996

For: Recombinant F1-V Plague Vaccine

* * * * *

#29
Luda
8/20/02

RULE 1.131 DECLARATION

Honorable Commissioner of
Patents and Trademarks
Washington, D. C. 20231

Sir:

We, Dr. David G. Heath, Dr. Arthur M. Friedlander, Dr.
George W. Anderson, Jr. and Dr. Susan L. Welkos, citizens of
the United States of America, do declare that:

1. We are the inventors of the above-referenced
application for patent filed on August 27, 1996;

2. Claims 1-3 and 5-17 of the above-referenced
application have been rejected over WO95/24475, (Titball et
al.-'75) publicly available on 14 September 1995.

3. We conceived and reduced to practice, in this
country, the invention claimed in the above-referenced
application prior to the publication date of Titball et al.
'75 document.

considered
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Prior to 14 September 1995, an F1-V fusion protein consisting of all of F1 and all of V was produced by recombinant DNA technology and purified.

Prior to 14 September 1995, a mouse assay for testing the immunogenicity and protective efficacy of the recombinant F1-V fusion protein was initiated.

Eight groups of 10 mice each were immunized with the recombinant F1-V at 13.6 ug in alhydrogel, 27.2 ug in alhydrogel, V in alhydrogel as a control, and alhydrogel alone as a control. After the second immunization, antibody response was measured, and the mice were then challenged with either the C092 or the C12 strain of *Y. pestis* via aerosol or subcutaneous route. The days of survival after challenge were recorded.

Result details from Dr. Andersons's laboratory notebook showing the days of survival of each mouse in the assay are presented in Exhibit A pages 1 and 2. While the dates have been blocked out on Exhibit A, the work described therein was initiated prior to 14 September 1995. The results indicate that mice immunized with the recombinant F1-V fusion protein survived challenge with *Y. pestis*. Therefore, the recombinant F1-V fusion protein provides protection against challenge with *Y. pestis*.

In re Appln. of Heath et al. -- 08/699,716

5. We declare further that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of the title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 27 July 02

David G. Heath
Dr. David G. Heath

Date: 29 July 02

Arthur M. Friedlander
Dr. Arthur M. Friedlander

Date: 29 July 02

George W. Anderson
Dr. George W. Anderson

Date: 29 July 02

Susan L. Welkos
Dr. Susan L. Welkos

[illegible]

For Animal Caretakers: Contact LTC Anderson, Office Ext 4933, Fax Ext 2152, Home (301) 473-5059 if you have any questions
Discard dead animals
Use scanner to check chip number of dead mice
Mark number of animals alive in each cage
re = mouse has been rechecked

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See page 39

0124-Jul-20022:43From-EXHIBIT H p. 111

MS 85-2002
24-Jul-2002
OFFICE

Date: 24-Jul-2002

Project: Recombinant F1-wholeV Fusion

Notebook # 85-2002-39

Species: Peripla pestis strain, CO92

Route: MS

Dose: 100 µl

Animal strain: Swiss Webster

Arrival: at 7-Bwks

Vendor: Harlan Sprague Dawley

Sex: female

Month	Day	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	Comments/Chip #
Group 7	LD50																															1F73175007/MV-041
	CO92																															1F63711872/MV-042
																																1F7CA2633E/MV-043
																																2008622CA7/MV-044
																																1F7F2E6057/MV-046
																																1F66752C6A/MV-048
																																1F5E776328/MV-047
																																1F4E480B46/MV-048
																																200E40084F/MV-048
																																200G1D2483/MV-060
																															No Chip	
Group 8	CO92																															No Chip
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